

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**75-374**

**CHEMISTRY REVIEW(S)**

1. CHEMISTRY REVIEW NO. 3

2. ANDA # 75-374

3. NAME AND ADDRESS OF APPLICANT

Altana Inc.  
60 Baylis Rd  
Melville, NY 11747

4. LEGAL BASIS FOR SUBMISSION

The applicant, Altana Inc., hereby certifies that, in their opinion and to the best of the applicant's knowledge, all listed patents claim in the United States for the reference listed drug psorcon (diflorasone diacetate) ointment, 0.05%, manufactured by Pharmacia & Upjohn have expired, and there is no period of marketing exclusivity for the reference list drug.

5. SUPPLEMENT(s)

Original 5/1/98

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Diflorasone Diacetate, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Amendment 5/15/98  
Amendment 10/23/98  
Amendment 10/29/98

10. PHARMACOLOGICAL CATEGORY

Anti-inflammatory

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF's 12607, 9025, 6473, 1627, 1572, 1725

13. DOSAGE FORM

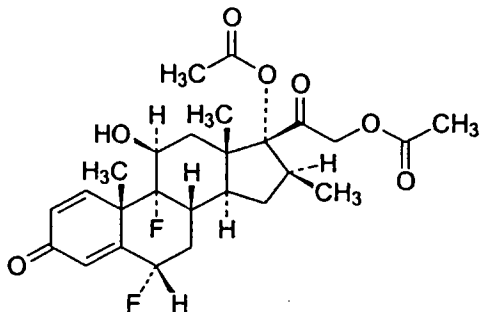
Ointment

14. POTENCY

0.05%

15. CHEMICAL NAME AND STRUCTURE

Diflorasone Diacetate. Pregna-1,4-diene-3,20-dione, 17,21-bis(acetyloxy)-6,9-difluoro-11-hydroxy-16-methyl-, (6 $\alpha$ ,11 $\beta$ ,16 $\beta$ )-. C<sub>26</sub>H<sub>32</sub>F<sub>2</sub>O<sub>7</sub>. M.Wt. 494.54. 33564-31-7. Anti-inflammatory, Glucocortic. USP 23, page 508.



16. RECORDS AND REPORTS

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

DATE COMPLETED:

Nashed E. Nashed, Ph.D.

4/8/99

Supervisor: Paul Schwartz, Ph.D.

4/9/99

Page(s) 10

Contain Trade Secret,  
Commercial/Confidential  
Information and are not  
releasable.

Chen Rev 3  
4/8/99